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Medtronic

August 17, 2001

By Fax to (301) 827-6801

Kimberly Littleton Topper
Food and Drug Administration, CDER,
Advisors and Consultants Staff, HFD-21
5600 Fishers Lane,
Rockville Maryland 20857

Re: Written Statement for Anesthetic and Life Support Drugs Advisory Committee
Docket 01N-0256
September 13 & 14, 2001 Meeting

Dear Advisory Committee Members:

Medtronic thanks the Anesthetic and Life Support Drugs Advisory Committee for the opportunity to express its views on the medical use of opiate analgesics in patients with chronic pain of nonmalignant etiology.

Medtronic is the world leader in medical technology providing lifelong solutions for people with chronic disease. Our mission is to contribute to human welfare by application of biomedical engineering in research, design, manufacture and sale of medical devices that alleviate pain, restore health, and extend life. Our products and therapies enhance or extend the lives of millions of people. Each year, 2.5 million patients benefit from Medtronic's technology.

Medtronic's Drug Delivery Business has developed the SynchroMed Infusion System. The SynchroMed pump is implanted subcutaneously to deliver morphine directly to the intrathecal space. Because the drug is delivered directly to the intrathecal space, pain can often be controlled with a small fraction of the dose that would be required with oral medication. (Typically, the intrathecal to oral morphine dose conversion is 1:300.[1])

The SynchroMed pump was approved by FDA in 1991 for chronic intrathecal or epidural infusion of preservative-free morphine sulfate for chronic, intractable pain of malignant or nonmalignant origin.

As with malignant pain, management of chronic non-malignant pain should proceed along a continuum, with less invasive therapies being tried first. Neuraxial drug delivery is reserved for intractable cases, before neurodestructive procedures. For these often-desperate patients, intrathecal pain therapy can bring pain relief that enables many to resume work, to care for their families, and to lead full, productive lives.

[1] Krames. E. Intraspinal Opioid Therapy for Chronic Nonmalignant Pain: Current Practice and Clinical Guidelines. Journal of Pain and Symptom Management. 1996,11(6):333-352.

The risks of diversion and abuse of opioids, while a significant concern with oral medications, is greatly reduced with intrathecal delivery via an implanted pump. The quantity of opioid used is much less than with oral dosing, and access is difficult (drug is refilled and withdrawn from the pump using a subcutaneous needle). Additionally, the pump tracks the amount of drug dispensed via the physician programmer, allowing for easy monitoring of the precise amount of drug consumed. The therapy is limited to an orphan population, further reducing the risk of diversion. Additionally, the highly trained neurosurgeons, anesthesiologists and other pain specialists who treat patients with intrathecal opioids are well aware of the abuse and diversion risks, and of the additional tracking and monitoring procedures required.

The potential for diversion and abuse of opioids must be weighed against the legitimate need of patients with intractable chronic pain. In particular, patients whose pain is so severe and disabling that they are willing to accept a surgically-implanted pump should not be denied a therapy that is their last resort prior to neurodestructive surgery.

As you consider the use of opioids in chronic, non-malignant pain, Medtronic urges the Advisory Committee Members and regulatory bodies to be mindful of these often-desperate patients. Medtronic asks that you do not take action that would restrict the ability of this orphan patient population to obtain relief. Thank you.

Sincerely,

Steve LaPorte
Vice President and General Manager
Medtronic Drug Delivery